

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF CALIFORNIA

ASSOCIATION FOR ACCESSIBLE
MEDICINES,

Plaintiff,

- against -

XAVIER BECERRA, in his official capacity
as Attorney General of the State of California,

Defendant.

Case No. 2:20-cv-01708-TLN-DB

REPLY IN SUPPORT OF
PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION

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1 The AG’s standing and ripeness arguments are belied by his own admissions; his Commerce
 2 Clause arguments are belied by binding precedent and AB 824’s text; and his remaining constitutional and
 3 injunctive-relief arguments lack merit. The Court should grant AAM’s motion for preliminary injunction.

4 ARGUMENT

5 I. The AG’s Standing Objections Are Meritless.

6 1. In AAM’s original challenge to AB 824, the Ninth Circuit held that AAM failed to establish that
 7 at least one of its members either “intend[s] to enter into settlement agreements of the sort prohibited by
 8 AB 824” or had already “incurred economic injury due to complying with [it], i.e., by foregoing pay for
 9 delay settlements or litigating patent-infringement suits to judgment.” *AAM v. Becerra*, 822 F. App’x 532,
 10 534 (9th Cir. 2020). AAM thereafter secured new declarations that do exactly as instructed. For example,
 11 the GC of one AAM member submitted a new declaration averring that the member recently “decided,”
 12 “in light of AB 824’s provision deeming exclusive licenses to be things of value” (and “at considerable
 13 cost in terms of legal fees”), “to pull out of” “a tentative settlement agreement under which the defendant
 14 would have received consideration and would have been allowed to bring its generic product onto the
 15 market prior to the expiration of the patent,” but “not immediately.” P.I. Ex. E (Dkt. 15-6) ¶¶ 4-5.¹

16 No more is required to satisfy Article III injury. *See, e.g., Nat’l Audubon Soc’y, Inc. v. Davis*, 307
 17 F.3d 835, 855-56 (9th Cir. 2002). Indeed, ***the AG admitted as much at oral argument***, conceding that it
 18 would “be enough” “[t]o establish standing” if AAM put forward a new “declaration from one of [its
 19 members]” saying that “we’re now in settlement negotiations ..., we’re trying to settle a case” via “one of
 20 these reverse payouts, but we’re scared to ... because we know ... we’ll then have to litigate [] with the
 21 \$20 million [minimum, per-person] penalty over our head.” P.I. Ex. A (Dkt. 15-2) at 19:5-20; *see id.* at
 22 19:18-20 (“Your Honor, I do think that brings them within [the] imminence that’s required[.]”).

23 Yet the AG now insists that “AAM has not met its burden” because “it is not clear whether the
 24 potential settlements that AAM describes in its declarations even come within the ambit of AB 824.”

25
 26 ¹ The AG argues that part of this (and other) testimony is inadmissible, but that objection is meritless.
 27 As explained in AAM’s attendant opposition—attached hereto as Exhibit 1—“the rules of evidence do
 28 not strictly apply to preliminary injunction proceedings,” *Immigrant Legal Res. Ctr. v. City of McFarland*,
 2020 WL 4593886, at *6 n.3 (E.D. Cal. Aug. 11, 2020), which is why courts overrule PI-stage evidentiary
 objections as a matter of course, *e.g., Faison v. Jones*, 440 F. Supp. 3d 1123, 1128 nn.1-2 (E.D. Cal. 2020).

Opp’n 4. That argument fails for a host of reasons. For one thing, Article III demands only that a plaintiff’s conduct be “*arguably proscribed*” by the law” he seeks to challenge. *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 162 (2014) (emphasis added). Furthermore, the AG does not argue that the declaration cited above, Exhibit E, refers to a settlement outside AB 824’s ambit. See Opp’n (Dkt. 20) at 3-4 (nitpicking Exs. B, C, D, and F, *but not E*). Nor could he. Under the now-scuttled settlement described therein, a generic manufacturer “would have received consideration,” including an “exclusive license[],” from the company asserting infringement, “and would have been allowed to bring its generic product onto the market prior to the expiration of the patent at issue in the case, but not immediately.” P.I. Ex. E ¶ 4. That is the archetype of a settlement regulated by AB 824: Under AB 824, a settlement (“an agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a pharmaceutical product”) “shall be a violation of this section if” a generic manufacturer “receives anything of value,” “including ... an exclusive license,” “from another company asserting patent infringement,” and “agrees to limit or forego ... sales of [its] product for any period of time.” § 134002(a)(1). So even if “more detail is needed” to decide whether AAM’s *other* declarations suffice (it is not), there can be no question that AAM has at least one declaration sufficient for Article III.

2. That injury is also fairly traceable to AB 824. Increased expenses or decreased revenue caused by compliance with a challenged statute “under the cloud of the civil statute’s penalties” constitute injury fairly traceable to the statute. *Bland v. Fessler*, 88 F.3d 729, 737 (9th Cir. 1996).² In trying to circumvent that black-letter law, the AG suggests that AAM’s members “have inflicted” all of their “present economic harm[s]” “on themselves.” Opp’n 6. But far from being self-inflicted, members’ “ongoing economic harm resulting from their cessation of” entering into patent settlements is “‘fairly traceable’ to [AB 824]” because they “reasonabl[y]” “expect[] that [the law] might be enforced against them.” *Davis*, 307 F.3d at 855-56. Indeed—more than reasonably. At oral argument in the Ninth Circuit, Judge Hurwitz asked the

² The AG argues that *Bland* “is factually distinct” because “here, *no* declarant has stated that they entered into an unlawful pay-for-delay agreement” and “there [is no] evidence of a ‘threat’ of enforcement.” Opp’n 5 n.6. But it is a matter of public record, of which this Court can take judicial notice, that AAM members have been losing defendants in *Actavis* cases. And as explained *infra*, the AG has admitted that he intends to enforce AB 824 against AAM’s members based on out-of-state settlements whenever there are “in-state sales” of the drugs covered by the settlements. P.I. Ex. A at 22:7–24:24.

AG point blank, “does California intend to enforce this statute in the case of agreements made out of state?” P.I. Ex. A at 22:10-12. After some back-and-forth, the AG finally answered, responding simply: “Yes.” *Id.* at 23:8-23. To say that the “fear that AAM members have of the [AG’s] enforcement of AB 824 against them is highly speculative,” Opp’n 5, or that AAM has failed to demonstrate sufficient “possibility of future harm,” *id.* at 6 (citation omitted), is thus to deny reality.³ AAM has standing.

II. The AG’s Argument That AAM’s Commerce Clause Claim Is Unripe Lacks Merit.

1. All three planks of the AG’s lack-of-ripeness argument are unsound. According to the AG, AAM’s “Commerce Clause claim is unripe” because “AAM has not demonstrated [a] that its members will engage in conduct that falls within the law’s scope, [b] that the Attorney General would have any reason to enforce AB 824 against them, or [c] that the law has been applied in a way that gives rise to any genuine threat of imminent enforcement.” Opp’n 1; *see also id.* at 7-8. The above discussion dispels points a and b: The AG does not (and cannot) contest that the settlement described in Exhibit E “falls within the law’s scope,” and the AG’s feigned lack of interest in enforcing the statute not only blinks reality, but flies in the face of the admission Judge Hurwitz painstakingly extracted from the Office. Furthermore, while the AG emphasizes that “*no* declarant has stated that they entered into an unlawful pay-for-delay agreement,” *id.* at 5 n.6, “[n]othing in [the Supreme] Court’s decisions requires a plaintiff who wishes to challenge the constitutionality of a law to confess that he will in fact violate that law,” *SBA List*, 573 U.S. at 163—especially when she has suffered economic injury due to complying with the law.

As for the third plank, the fact that California has not yet enforced AB 824 cannot logically pose a barrier to jurisdiction in a case like this one. After all, AB 824 has been the subject of a federal challenge

³ The AG’s insistence that his admissions in the Ninth Circuit were merely “about the *merits* of AAM’s dormant Commerce Clause challenge” and “the scope of AB 824,” Opp’n 5-8, is spurious. Judge Hurwitz could not have been clearer that he was “not asking” for “a description of the statute” and “not looking for the legal argument” regarding whether it would be “a dormant commerce clause problem” if the AG “enforce[d] this law with respect to agreements made outside the borders of California.” P.I. Ex. A at 22:18-23, 23:14-22. He was asking a simple question: Does the AG “intend to enforce this against out-of-state agreements”? *Id.* at 23:14-18. The AG’s current position is thus contradicted by the record. It also is belied by AB 824’s evident intent to influence the terms of settlements and expose parties to enormous penalties if the terms fall on the wrong side of an AG-drawn line. Given those objectives, it is disingenuous to claim that members face no threat even if their contemplated agreements include an exclusive license or another thing of value not specifically blessed by AB 824’s narrow carve-out.

every day it has been operative. To require a plaintiff in this posture to show that the challenged law **already** “has been applied,” Opp’n 1, 8, would be to preclude pre-enforcement challenges to new state statutes—which is why that is not the law. *See SBA List*, 573 U.S. at 158 (an “enforcement action is not a prerequisite to challenging the law”). Rather, enforcement history “has little weight” when, as here, the challenged law “is relatively new.” *Wolfson v. Brammer*, 616 F.3d 1045, 1060 (9th Cir. 2010).

More fundamentally, the AG’s basic framework is incorrect. While this Court applied the three-part ripeness framework on which the AG relies in the prior round of litigation, that was because AAM had not proven that any member had suffered economic injury—which meant that members’ injuries had to be “grounded on the contention that [California] could exercise its discretion to [enforce AB 824]” against them “some time” in the future. *Coons v. Lew*, 762 F.3d 891, 898 (9th Cir. 2014). But that is no longer true. As explained, AAM’s injuries now are grounded in the “actual, ongoing economic harm” that **members already suffered** as a result of walking away from settlements regulated by AB 824 and continuing to litigate instead. *See Davis*, 307 F.3d at 855-56. And when, as here, the basis “of the suit is” not “threatened prosecution” but rather “economic injury” from “cessation of [regulated conduct],” a court “need not rely on the three-factor test” around which the AG organizes its argument, as a case is ripe by definition. *Id.* Indeed, the AG does not cite a single case deeming claims unripe where the plaintiff had **already suffered economic harm** fairly traceable to the challenged law. That is because there is none.⁴

2. Turning to prudential ripeness, AAM’s members’ “injury is established, and the legal arguments are as clear as they are likely to become.” *Id.* at 857. The Supreme Court has held that “plaintiffs’ claims are suitable for judicial review” when the government merely declines an invitation to argue “that plaintiffs will not be prosecuted if they do what they say they wish to do.” *Holder v. Humanitarian Law Project*, 561 U.S. 1, 16 (2010). *A fortiori*, claims are suitable for judicial review when, as here, the government admits in open court that it intends to enforce the challenged statute as written if the plaintiffs do as they

⁴ The AG argues that because one trapper in *Davis* “had ‘been arrested and prosecuted’ for violating the challenged law,” *Davis* cannot displace the three-factor test. Opp’n 7 n.10. That fundamentally misunderstands the law. “The three-factor test applied in both *San Diego Guns* and *Thomas* was premised on the plaintiffs’ assertion that a ‘risk of prosecution’ was the injury.” *Davis*, 307 F.3d at 855. But when (as here) the injury “is not a hypothetical risk of prosecution but rather actual, ongoing economic harm resulting from their cessation of [regulated conduct],” courts “need not rely on the three-factor test.” *Id.*

wish to do and when, as here, the plaintiffs have already suffered economic injury as a direct result of forbearing from that conduct. So regardless of where prudence pointed in the prior litigation, prudence is now firmly on AAM's side: The issues presented by AAM's Commerce Clause challenge this time around are purely legal and turn solely on the extraterritorial reach established by the text of AB 824.⁵

3. Finally, the AG describes AAM's Commerce Clause claim differently depending upon what suits his argument, but uniformly misdescribes it. In one place, the AG argues that the claim is a typical "as-applied challenge," in which case, he says, a "factual record[]" is needed. Opp'n 9 (emphasis omitted). Elsewhere, the AG suggests that the claim is really a "facial challenge," in which case, he says, "[AAM] must establish 'that no set of circumstances exists under which the [AB 824] would be valid.'" *Id.* at 7 n.9 (alterations in original; emphases omitted; citation omitted). Neither is quite right. To be sure, AAM's claim is "'as applied' in the sense that it does not seek to strike [AB 824] in all its applications, but only to the extent it" applies to settlements completed wholly out of state. *Doe v. Reed*, 561 U.S. 186, 194 (2010). But it also "is 'facial' in that it is not limited to [a] particular case, but challenges application of the law more broadly," *i.e.*, to **all** settlements completed wholly out of state. *Id.* Accordingly, the question is whether AAM can "satisfy [the] standards for a facial challenge **to the extent of th[e] reach**" that AAM is seeking to have the law enjoined, *id.* (emphasis added), namely, to settlements completed wholly outside of California. The answer to that question is plainly "yes," as explained below.

III. AB 824 Violates The Dormant Commerce Clause.

States are prohibited from "regulating commerce occurring wholly outside [their] borders," **even if** the out-of-state commerce "has effects within the State." *Healy v. Beer Inst.*, 491 U.S. 324, 332, 335-36 (1989). Yet "regulating commerce occurring wholly outside [California's] borders" is exactly what AB 824 does. If two parties settled a patent suit in Delaware on terms that AB 824 deems unlawful, then those parties (and every person who assisted them in getting the settlement done) would find themselves liable for massive penalties under AB 824. The statute is thus a textbook violation of the dormant

⁵ The AG contends that AAM's "declarants do not indicate whether California sales would be included in the alleged potential settlements." Opp'n 8. Even assuming that that "is necessary to make AB 824 applicable," *id.*, it is a matter of public record that all FDA-approved generics are sold in California, the largest market in the Nation. *See, e.g.*, Medicare & Medicaid Guide ¶ 180736, 2008 WL 11388482.

Commerce Clause. After all, the very definition of “directly regulat[ing]” in violation of the dormant Commerce Clause is “impos[ing] civil or criminal penalties on non-compliant transactions completed wholly out of state.” *Rocky Mountain Farmers Union v. Corey*, 730 F.3d 1070, 1101-03 (9th Cir. 2013).

1. The AG’s arguments to the contrary are inconsistent with the statute and the governing doctrine. First of all, AB 824 does not “simply alter[] the presumption and penalties applicable to conduct that was already illegal under California law.” Opp’n 10; *see also id.* at 11.⁶ AB 824 creates a new violation of the Health and Safety Code with a distinct statute of limitations and a distinct set of reporting requirements, which is far more than tinkering with an extant regime. Nor is AB 824 a carbon copy of the Cartwright Act. Whereas “the ‘transaction or occurrence’ proscribed by the Cartwright Act includes not only the sale of price-fixed goods, but the full extent of incipient conspiratorial conduct described in section 16720 of the Act” (which usually will include conduct *in the state*), *AT&T Mobility LLC v. AU Optronics Corp.*, 707 F.3d 1106, 1110 (9th Cir. 2013), *only* a patent settlement, *not subsequent sales of drugs*, can violate AB 824. *See* § 134002(a); *see also* P.I. Ex. A at 28:14-20 (JUDGE HURWITZ: “[T]he statute ... regulate[s] the entering into the agreement, ... [n]ot the subsequent marketing in California.”). To say that AB 824 merely tinkers with state antitrust law is thus to misdescribe the statute at a fundamental level.

2. In all events, state antitrust law is not exempt from the dormant Commerce Clause. No federal court of appeals has ever held that a state can apply its state antitrust law to directly regulate an agreement that was completed wholly out of state just because that agreement has in-state effects. In fact, *every* court of appeals to confront the issue head-on has reached the same conclusion: A “state [antitrust law] cannot regulate [transactions] that take place wholly outside it.” *In re Brand Name Prescription Drugs Antitrust Litig.*, 123 F.3d 599, 613 (7th Cir. 1997). That includes the Ninth Circuit in *Knevelbaard Dairies v. Kraft Foods, Inc.* (cited at Opp’n 9-10), which held that California’s “antitrust and unfair competition statutes”

⁶ The AG admitted to the Ninth Circuit that AB 824 does more than merely tweak a presumption. While the AG initially asserted that “AB 824 merely creates rebuttable presumptions,” Judge Ikuta pointed out that § 134002(a) in fact “says that this type of pay-for-delay agreement shall be presumed to have an anti-competitive [effect] *and shall be a violation of this section*” and that the statute imposes “minimum \$20 million” penalties for violations. P.I. Ex. A at 16:5-21 (emphasis added). Judge Ikuta followed up that accurate description with an accurate conclusion—“So, it’s not merely shifting the burden.”—to which the AG grudgingly responded, “correct.” *Id.* at 16:21-23. That was not a slip of the tongue; it was entirely consistent with the text of the statute and the AG’s long-held (but misguided) view of its authority.

could be applied “consistent with the Commerce Clause” *only because* “[t]he conduct complained of” in the case “took place not only in Wisconsin, where [one part of the scheme] was located, *but in California*” *too*. 232 F.3d 979, 993-94 (9th Cir. 2000) (emphasis added). But unlike the Cartwright Act, which makes both upstream activity (*e.g.*, agreements) and downstream activity (*e.g.*, sales) cognizable conduct, *see AT&T Mobility*, 707 F.3d at 1110, the only thing that can violate AB 824 is a settlement, *not* the subsequent sale of a product covered by it. “[A]greement[s] resolving or settling ... patent infringement claim[s]” (*i.e.*, patent settlements) are *all* that AB 824 regulates. § 134002(a)(1); *see also* P.I. Ex. A at 28:4-5. Accordingly, if a patent settlement is completed out of state, then California lacks power to regulate it under AB 824, even if the settlement “has effects within the State.” *Healy*, 491 U.S. at 336.

3. It is also quite wrong to describe AB 824 as merely “set[ting] the terms of doing business in California (and no other state).” Opp’n 11. The AG himself explains why: “As the plain language of the statute makes clear, AB 824 ... applies to agreements[.]” *Id.* at 10. The fact that “AB 824 does not apply to out-of-state *sales*,” *id.* at 12 (emphasis added), is thus entirely irrelevant, for the statute very much does regulate out-of-state *settlement agreements*. *See* § 134002(a). And if penalizing private parties for entering, out of state, into a patent settlement agreement that the AG deems insufficiently procompetitive is not setting the terms of business in another state, then the dormant Commerce Clause has no meaning.

The AG tries to square that circle by arguing that he cannot enforce AB 824 until a sale covered by a settlement is made in California. But even if that were correct as a matter of statutory construction and/or state law, it would make no difference for purposes of the Commerce Clause; the “mere fact that” a state law is “triggered only by [in-state] sales ... does not validate the law if it regulates ... out-of-state transactions.” *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 580 (1986). Nor does it make a difference that the statute “seeks to prevent or reduce anticompetitive pharmaceutical sales *in California*.” Opp’n 10 (emphasis added). That much is clear from *Baldwin*, which (despite the AG’s efforts to reconceptualize it as only about protectionism) struck down a state law because it regulated wholly out-of-state transactions. *Baldwin v. G.A.F. Seelig, Inc.*, 294 U.S. 511, 521-23 (1935). Indeed, this case is *a fortiori* of *Baldwin*. Like AB 824, the state law at issue in *Baldwin* was intended to protect in-state consumers: “The end to be served [was] the maintenance of a regular and adequate supply of pure and wholesome milk.” *Id.* at 523. And whereas (the AG claims) AB 824 applies only once a drug covered

by an out-of-state transaction (*i.e.*, settlement) is sold in California, the New York law in *Baldwin* applied only to transactions involving products *specifically intended for resale in New York*. *Id.* at 521. Yet that did not save the statute, for it regulated transactions completed in other states, and the Commerce Clause “precludes the application of a state statute to commerce that takes place wholly outside of the State’s borders, whether or not the commerce has effects within the State.” *Healy*, 491 U.S. at 336.⁷

4. Finally, there is no “require[ment]” that, “to bring a dormant Commerce Clause challenge,” a plaintiff must “present[] evidence that ‘conflicting, legitimate legislation is already in place.’” Opp’n 12. The existence of conflicting legislation may *support* an extraterritoriality claim, but it is *not a prerequisite*. On the contrary, a state law such as AB 824 “that directly controls commerce occurring wholly outside the boundaries of a State *exceeds the inherent limits of the enacting State’s authority and is invalid* regardless of whether the statute’s extraterritorial reach was intended by the legislature” and regardless of the statute’s effect on interstate commerce. *Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1323-24 (9th Cir. 2015) (en banc) (quoting *Healy*, 491 U.S. at 336). The requirement the AG seeks to impose would mean that the en banc decision in *Sam Francis* was wrongly decided. In reality, *Sam Francis* is both correct and binding—and it compels the conclusion that AB 824 is unconstitutional.

IV. AAM Is Likely To Succeed On Its Remaining Claims As Well.

A.1. The AG admits that AB 824 deems exclusive licenses presumptively unlawful, but argues that that does not matter because AB 824 “does not reach exclusive licenses unless the license is given to induce a rival to agree not to compete.” Opp’n 13. But (a) there is no such inducement requirement in the statute, and (b) an “agree[ment] not to compete” is literally what an *exclusive* license is. The fact that an exclusive license that did not have a delayed entry date (which is quite unlikely) would not be within

⁷ The AG argues that “if manufacturers want to avoid application of AB 824 to agreements they enter into, they can do so simply by omitting California sales from those covered by the agreement.” Opp’n 11. The simple response is: No, they can’t. The agreements AB 824 regulates do not “cover[]” sales; they dictate when a generic may enter the market. An agreement could “omit[] California sales from those covered by [it]” only by allowing the generic onto the market *immediately in California*. More important, even if two parties entered into such an unworkable settlement, that *still* would not exempt them. Manufacturers sell their products to wholesalers, which sell them to pharmacies or hospitals, which dispense them to patients. A brand-name drug covered by an agreement that “omit[s] California sales” could thus wind up being sold in California at a price the AG deems unacceptable, in which case he could sue the manufacturers under AB 824 even though they did not sell any such product in the state.

the scope of the bill, *see id.*, therefore makes no difference, and the conflict between AB 824 and section 261 of the Patent Act could not be starker. As for section 282(a), the AG insists that AB 824’s prohibition on presuming “[t]hat any patent is enforceable” (§ 134002(b)(2)) is consistent with the Patent Act because “validity” (which section 282(a) requires courts to “presume[.]”) and “enforceability” (which AB 824 prohibits courts from presuming) are not the same thing. Opp’n 13-14. But the AG offers little support for his suggestion that § 134002(b)(2) only means to refer to technical enforceability (*i.e.*, “whether the patent was procured by fraud or wrongdoing”). *Id.* And in all events, “[p]olicing fraud against federal agencies is hardly ‘a field which the States have traditionally occupied,’” as the AG admits. *Id.* at 14 n.17 (quoting *Buckman Co. v. Pls.’ Legal Comm.*, 531 U.S. 341, 347 (2001)). Indeed, the Federal Circuit has held not only that the question whether a patent “was procured by fraud” is an issue of federal law, but that it is an issue that falls under the Federal Circuit’s exclusive jurisdiction. *See Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1067-68 (Fed. Cir. 1998). Accordingly, under the AG’s own reading of § 134002(b)(2), the statute is *still* in direct conflict with federal law.

2. The AG misreads *Actavis*, misdescribes the Supreme Court’s preemption cases, and misunderstands the Hatch-Waxman Act. But given this Court’s familiarity with those issues, AAM is content to rest on its Memorandum on those points and use its limited space on the BPCIA. While the AG accurately recounts the holding of *Amgen, Inc. v. Sandoz, Inc.*, 877 F.3d 1315 (Fed. Cir. 2017), he presents no affirmative argument; he simply asserts that no case amounts to “a blanket ruling that states cannot regulate drug sales within the state.” Opp’n 16. That is true, but—again—**AB 824 does not regulate drug sales**; it regulates settlements. To the extent those agreements deal with biologics, AB 824 is preempted.

B. The AG does not dispute that AB 824 allows him to seek “a \$20 million penalty against an individual.” *Id.* at 18 n.20. And there is simply no argument that a \$20-million penalty could ever be constitutional vis-à-vis an individual “person” who merely “assists” in a settlement effort and who does not receive “anything of value” therefrom. § 134002(e)(1)(A). So while the AG notes that one of AB 824’s penalty provisions applies to “parties” and that “[t]he parties to [] agreements are pharmaceutical companies, not natural persons,” Opp’n 18, the fact that he does not disavow his flatly unconstitutional statutory authority to impose multimillion-dollar penalties on individuals is telling—and it crystallizes both the stakes of this case and the immediacy of the dispute.

Nor is the AG correct that AAM's Excessive Fines claim is a mere "as-applied" challenge that cannot be brought until after the AG actually tries to impose such a penalty. *See id.* at 17, 18 n.20. As AAM explained in its Memorandum, the claim is that there is *no set of circumstances* under which the *minimum* \$20-million penalty could constitutionally be applied to a person who has not received anything of value as a result of her assistance. *See Doe*, 561 U.S. at 194. No further facts are needed to answer that question. Nor is there any prudential reason to postpone adjudication. Despite the AG's assertion that "there would be nothing to prevent [an] individual from raising an Excessive Fines Clause claim" after the AG "sought a \$20 million penalty against [her]," Opp'n 18 n.20, that individual would have *no avenue* to get into federal court to challenge the constitutionality of AB 824's penalties, given *Younger*.

C. AB 824 violates due process. States may not impose liability without providing a meaningful "opportunity to present every available defense." *Philip Morris USA v. Williams*, 549 U.S. 346, 353 (2007). Yet, under AB 824, the most basic defense is effectively eliminated by its stacked presumptions.

V. The Remaining Factors Weigh In Favor Of AAM And Injunctive Relief.

The AG's undifferentiated statistics cannot change the sworn testimony before this Court that multiple AAM members have lost and/or walked away from valuable settlement offers as a direct result of AB 824, and that multiple members are continuing as we speak to spend money litigating that they would not have spent but for AB 824. That economic injury, which is ongoing, is textbook irreparable harm due to the Eleventh Amendment—and doubly so given AB 824's unconstitutionality. Only an injunction can prevent AAM members from suffering further irreparable harms. In contrast, *not* enjoining AB 824 will keep intact the status quo, under which manufacturers are not settling certain patent cases, which means that certain life-saving generic medicines that would be coming onto the market pre-patent-expiry under pre-AB-824 settlements are now staying off the market much longer, as a direct result of AB 824. Finally, given that (a) the AG will be still able to police in-state conduct (and will still be able to challenge allegedly anticompetitive settlements under federal law) even if AB 824 were off the books, and (b) no government has a legitimate interest in enforcing unconstitutional laws, the AG would not be harmed by an injunction preventing enforcement of AB 824. The case for an injunction is therefore clear.

CONCLUSION

The Court should grant AAM's motion for preliminary injunction.

Respectfully submitted,

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